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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,811	06/14/2006	Michael P. Doyle	31725-200230	8735
23643 7590 12/10/2009 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204				
EXAMINER				
WARE, DEBORAH K				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
12/10/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

### Office Action Summary

**Application No.**

10/582,811

**Applicant(s)**

DOYLE ET AL.

**Examiner**

DEBBIE K. WARE

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 7-17, 19-23, 25-27, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13 is/are allowed.
- 6) ☒ Claim(s) 1, 25-27, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 14-17, 19-23, 26, 27, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Proficiency's Patent Drawing Review (PTO-544)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 7-17, 19-23, 25-27 and 29-30 are pending.

#### ***Response to Amendment***

The amendment filed September 9, 2009, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

Claim 26 is objected to for being a substantial duplicate of claim 17, and it is suggested to include at line 4, after "comprising" the following --at least one of--or cancel claims 26, 27 and 29-30.

Furthermore, it is suggested to insert at line 3, after "comprising" of claim 14, the following --at least one of-- and to change dependency of claim 16 from "claim 15" to --claim 14-- .

Further, all of the dependent claims from each of claims 14, 16, 17 and 26 are objected to for being dependent from objected-based claims. Therefore, claims 14-17, 19-23, 26, 27, 29 and 30 are all objected to for the above reasons noted for each of claims 14, 16 and 26.

The steps of "contacting" and "administering" are not considered to be substantially different from one another which makes claims 26 and 17 substantial duplicates of each other.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A product of nature is not patentable subject matter and an isolated microorganism is not substantially isolated from nature as required by ATCC depository strains as now claimed. Hence, it is suggested that the term "isolated" be replaced with –biologically pure—in order to properly indicate the purity of the newly claimed strains.

***Declaration Under 37 CFR 1.132***

The Declaration and Exhibit A under 37 CFR 1.132 filed September 9, 2009, is sufficient to overcome the rejection of claims 1, 7-17, and 19-23 based upon Stern et al applied under 35 USC 102/103 in the last Office action. However, the Declaration and Exhibit A under 37 CFR 1.132 filed September 9, 2009, is insufficient to overcome the rejection of claims 25-27 and 29-30 based upon Stern et al applied under 35 USC 102/103 as set forth in the last Office action because: claims 25, 26-27 and 29-30 read on a product produced by *Lactobacillus salivarius* bacteria; and although, the claims are limited to specific strains which are novel over the cited prior art based upon the Declaration and Exhibit A, the claims read on a product which is not considered to be different and novel from that disclosed by Stern et al. Stern et al teach a product produced by *Lactobacillus salivarius* of which performs the identical function as claimed.

The disclosed product and claimed product have not been shown to be different from each other. Therefore, the Declaration and Exhibit A do not remove the cited prior art over the claims 25, 26-27 and 29-30.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-27 and 29-30 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stern et al, cited on enclosed PTO-1449 Form.

Claims are drawn to isolated microorganisms of *Lactobacillus salivarius* and compositions containing them and methods using the compositions for inhibiting and reducing levels of *Campylobacter* and *Salmonella* in poultry.

Stern et al teach isolated microorganisms of *Lactobacillus salivarius* and compositions containing them and methods using the compositions for inhibiting and reducing levels of *Campylobacter* and *Salmonella* in poultry. Note col. 6, lines 30-32, lines 37-38, line 52 and col. 12, lines 56-57.

The claims are identical to the cited disclosure of Stern et al and are, therefore, considered to be anticipated by the teachings therein. However, in the alternative that the isolates are shown to be different than those of the disclosure of the cited reference then such difference is considered to be so slight as to render the claims obvious over the teachings of Stern et al. It would have been obvious to select for an isolate of *Lactobacillus salivarius* to provide a composition to carry out methods for inhibiting *Salmonella* and *Campylobacteria* in poultry because the reference teaches that these isolates have been used for the same purpose. Hence each of the claimed features are anticipated by the cited reference or would have been obvious from the teachings of the Stern et al reference. The claims are alternatively rendered *prima facie* obvious over Stern et al.

### ***Response to Arguments***

Applicant's arguments filed September 9, 2009, have been fully considered but they are not persuasive. Claims 25-27 and 29-30 do not necessarily require the strain but alternatively require only a product which can be produced by *Lactobacillus*

salivarius of which the product as claimed is disclosed by Stern et al, such as bacteriocin and the like. The product has the identical functions and properties of the disclosed product and is, therefore, considered to be anticipated by the teachings of the reference. Two different strains of a genus species can produce the same product and it is the product itself which must be patentable. Exhibit A establishes different strains of Lactobacillus salivarius, etc. but not different products. Thus, the rejection is sustained and it is suggested to delete "or a product produced by said bacteria" which occurs at the last line of claim 25 and at the second to last line of claim 26.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

Claims 7-13 are indicated to be allowable subject matter pending the outcome of a patentability conference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/  
Deborah K. Ware  
Examiner  
Art Unit 1651  
/David M. Naff/  
Primary Examiner, Art Unit 1657